EXHIBIT B

DEFENDANT MERCK & CO., INC.'S ANSWER TO PLAINTIFF'S UNVERIFIED COMPLAINT AND REQUEST FOR JURY TRIAL

A limited liability partnership formed in the State of Delaware

REED SMITH LLP

GENERAL DENIAL

1. Answering plaintiff's unverified Complaint, defendant Merck & Co., Inc., ("answering defendant") generally and specifically denies every allegation of the Complaint, and the whole thereof, and denies that plaintiff was injured or damaged in any sum, or at all, by reason of any act or omission of answering defendant or anyone acting on its behalf.

AFFIRMATIVE DEFENSES

- 2. As a first affirmative defense, answering defendant alleges that the Complaint fails to state facts sufficient to constitute a cause of action against this answering defendant.
- 3. As a second affirmative defense, answering defendant alleges that this Court lacks personal jurisdiction over answering defendant.
- 4. As a third affirmative defense, answering defendant alleges that California's judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and an undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.
- 5. As a fourth affirmative defense, answering defendant alleges that to the extent that plaintiff asserts claims based on answering defendant's alleged adherence or lack of adherence to and compliance with applicable federal laws, regulations, and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

- 6. As a fifth affirmative defense, answering defendant alleges that plaintiff may have failed to exercise reasonable care to mitigate her alleged damages.
- As a sixth affirmative defense, answering defendant alleges that the provisions of 7. California Civil Code Section 1431.2 are applicable to the Complaint and each cause of action therein.
- 8. As a seventh affirmative defense, answering defendant alleges that plaintiff's claims are barred in whole or in part by the applicable statutes of limitations, including but not limited to California Code of Civil Procedure Sections 335.1 and 338 and former section 340(3), California Business and Professions Code Section 17208, and California Civil Code Section 1783.
- 9. As an eighth affirmative defense, answering defendant alleges that the subject pharmaceutical product manufactured or distributed by answering defendant has at all relevant times been available only upon the prescription of a licensed physician, and plaintiff's prescribing physicians stood in the position of the learned intermediaries between answering defendant and plaintiff. To the extent that plaintiff asserts claims based on an alleged failure by answering defendant to warn plaintiff directly of alleged dangers associated with the use of the subject pharmaceutical product manufactured or distributed by answering defendant, such claims are barred because answering defendant has discharged its duty to warn in its warnings to the prescribing physicians, under the learned intermediary doctrine.
- 10. As a ninth affirmative defense, answering defendant alleges that plaintiff's claims are barred in whole or in part because the subject pharmaceutical product manufactured or distributed by answering defendant is a prescription medication which is "unavoidably unsafe" within the meaning of Comment k to Section 402A of the Restatement (Second) of Torts.

12

13

14

15

16

17

18

19

20

21

. 22

23

24

25

26

27

1

11. As a tenth affirmative defense, answering defendant alleges that plaintiff's claims are barred in whole or in part because answering defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product manufactured or distributed by answering defendant within the meaning of Comment i to Section 402A of the Restatement (Second) of Torts.

- 12. As an eleventh affirmative defense, answering defendant alleges that plaintiff's claims are barred in whole or in part because the subject pharmaceutical product manufactured or distributed by answering defendant "provides net benefits for a class of patients" within the meaning of Comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.
- 13. As a twelfth affirmative defense, answering defendant alleges that the subject pharmaceutical product manufactured or distributed by answering defendant, and the design, manufacture, and promotion thereof, conformed to the state-of-the-art for the design, manufacture, and promotion of such, or similar products based on available medical and scientific knowledge.
- As a thirteenth affirmative defense, answering defendant alleges that plaintiff's 14. claims are barred in whole or in part under the applicable state law because subject pharmaceutical product manufactured or distributed by answering defendant was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.
- As a fourteenth affirmative defense, answering defendant alleges that plaintiff's 15. claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product manufactured or distributed by answering defendant under applicable federal laws, regulations, and rules.

	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0

2

3

4

5

As a fifteenth affirmative defense, answering defendant alleges that the subject 16. pharmaceutical product manufactured or distributed by answering defendant complied with the applicable laws, regulations, and rules promulgated and enforced by the Food and Drug Administration. Compliance with such laws, regulations, and rules demonstrates that due care and reasonable prudence were exercised in the design, manufacture, and promotion of the subject pharmaceutical product and that the subject pharmaceutical product was not defective in any respect.

As a sixteenth affirmative defense to each cause of action in the Complaint, 17. answering defendant alleges that plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

A limited liability partnership formed in the State of Delaware

REED SMITH LLP

18. As a seventeenth affirmative defense, answering defendant alleges that if plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss was only so sustained after plaintiff knowingly and voluntarily assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by answering defendant and prescribed by the plaintiff's physicians.

19. As an eighteenth affirmative defense, answering defendant alleges that if plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss may have been directly and proximately caused by the operation of nature or the intervening or superseding acts of persons not having real or apparent authority to take said actions on behalf of answering defendant, over whom answering defendant had no control, and/or for whom answering defendant may not be held accountable.

26

23

24

25

27

A limited liability partnership formed in the State of Delaware

REED SMITH LLP

20.	As a nineteenth affirmative defense, answering defendant alleges that plaintiff ma
have been c	areless and negligent in the matters alleged, thereby causing and contributing to any
alleged inju	ry, damage, or loss to plaintiff.

- 21. As a twentieth affirmative defense, answering defendant alleges that if plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss may have been caused by parties other than answering defendant, or third persons not parties to this action, who may have been negligent, legally responsible, or otherwise at fault. In the event of a finding of liability in favor of plaintiff, a settlement, or a judgment against answering defendant, answering defendant requests an apportionment of fault among all parties and third persons as permitted by Li v. Yellow Cab Company and America Motorcycle Association v. Superior Court. Answering defendant also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.
- 22. As a twenty-first affirmative defense, answering defendant alleges that if plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss resulted from pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions, idiosyncratic reactions, or natural course of conditions for which answering defendant is not responsible.
- 23. As a twenty-second affirmative defense, answering defendant alleges that plaintiff's claims are barred under Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.
- 24. As a twenty-third affirmative defense, answering defendant alleges that if plaintiff has sustained injury or loss as alleged in the Complaint, such injury or loss may have been proximately caused by plaintiff's misuse or abuse of subject pharmaceutical product manufactured or distributed by answering defendant.

A limited liability partnership formed in the State of Delaware

REED SMITH LLP

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

26

27

	25.	As a twenty-fourth affirmative defense, answering defendant alleges that plaintiff's
claims	are bar	red in whole or in part by the First Amendment of the United States Constitution
and sir	nilar pı	rovisions in the Constitution of the State of California which protect, among other
things,	answe	ring defendant's right to promote and advertise the subject pharmaceutical product.

- 26. As a twenty-fifth affirmative defense, answering defendant alleges that plaintiff's claims are barred in whole or in part by the doctrines of accord and satisfaction, good faith, consent, res judicata, payment and release, waiver, collateral estoppel, judicial estoppel, equitable estoppel, unclean hands, and/or laches.
- As a twenty-sixth affirmative defense, answering defendant alleges that plaintiff's 27. claims are barred in whole or in part because all acts or omissions by answering defendant (or its agent or representative) were privileged or justified and any claim based thereon is barred.
- 28. As a twenty-seventh affirmative defense, answering defendant alleges that plaintiff's claims are barred in whole or in part because plaintiff lacks standing to bring such claims.
- As a twenty-eighth affirmative defense, answering defendant alleges that plaintiff's 29. claims are barred in whole or in part because the Complaint fails to join necessary and indispensable parties.
- As a twenty-ninth affirmative defense, answering defendant alleges that plaintiff's 30. claims are barred in whole or in part because they have been improperly joined in this action.
- As a thirtieth affirmative defense, answering defendant alleges that plaintiff's 31. claims are barred in whole or in part because they have been filed in an improper venue.

7

33.

10

11 12

13

14

15

A limited liability partnership formed in the State of Delaware

REED SMITH LLP

16 17

18 19

20 21

22 23

24

25

26

27

32. As a thirty-first affirmative defense, answering defendant alleges that to the extent plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

As a thirty-second affirmative defense, answering defendant alleges that to the extent that plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to plaintiff; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to answering defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1, 111 S.Ct. 1032 (1991); TXO Production Corp. v. Alliance Resources, Inc.,

2

3

4

5

6

7

8

9

10

11

23

24

25

26

27

509 U.S. 443, 113 S.Ct. 2711 (1993); BMW of North America, Inc. v. Gore, 517 U.S. 559, 1	16
S.Ct. 1589 (1996); and State Farm Ins. Co. v. Campbell, 123 S.Ct. 1513 (2003).	

- 34. As a thirty-third affirmative defense, answering defendant alleges that to the extent that plaintiff seeks punitive damages for an alleged act or omission of answering defendant, no act or omission was oppressive, fraudulent, or malicious, under California Civil Code Section 3294, and therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code Section 3294(b).
- 35. As a thirty-fourth affirmative defense, answering defendant alleges that plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because answering defendant's conduct and all activities with respect to the subject pharmaceutical product manufactured or distributed by answering defendant were lawful, fair, truthful, not misleading or deceptive, and were justified based on the state of medical and scientific knowledge available during the relevant time period.
- 36. As a thirty-fifth affirmative defense, answering defendant alleges that plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because all of answering defendant's activities as alleged in the Complaint were in compliance with the applicable laws, regulations, and rules, and thus cannot be deemed unlawful, unfair, fraudulent, deceptive, untrue, or misleading.
- 37. As a thirty-sixth affirmative defense, answering defendant alleges that plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500, et seq. are barred in whole or in part because plaintiff does not qualify as private attorney general, and for that reason and others, plaintiff lack standing to prosecute a claim for injunctive or monetary relief.

2

3

11

14

A limited liability partnership formed in the State of Delaware

REED SMITH LLP

19

17

21

.22

23

- 38. As a thirty-seventh affirmative defense, answering defendant alleges that plaintiff's claims under Business and Professions Code Sections 17200, et seg, and 17500, et seg, are barred in whole or in part because there is no basis for injunctive relief in this action.
- 39. As a thirty-eighth affirmative defense, answering defendant alleges that plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500 et seq. are barred in whole or in part by the doctrine of primary jurisdiction in that the subject pharmaceutical product manufactured or distributed by answering defendant and any advertisement regarding such product are regulated by the Food and Drug Administration and as such, answering defendant requests that this court, sitting in equity, abstain from hearing claims under Sections 17200 et seq. and 17500 et seq.
- 40. As a thirty-ninth affirmative defense, answering defendant alleges that plaintiff is not entitled to relief under Business and Professions Code Sections 17200, et seq. and 17500 et seq. because plaintiff has an adequate remedy at law.
- 41. As a fortieth affirmative defense answering defendant alleges that plaintiff's claims under Business and Professions Code Sections 17200, et seq. and 17500 et seq. are barred in whole or in part under principles of substantive and procedural due process.
- 42. As a forty-first affirmative defense, answering defendant alleges that to the extent plaintiff seeks restitution on behalf of individuals who used the subject pharmaceutical product manufactured or distributed by answering defendant and suffered no damage or loss as a result thereof, restitution is unavailable as nothing has been taken from those individuals, who allegedly could have an equitable basis for restitution.
- 43. As a forty-second affirmative defense, answering defendant alleges that plaintiff's claims for restitution for products previously used are barred in whole or in part because plaintiff

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

. 22

23

24

25

26

27

28

or plaintiff's decedent received benefits from the subject pharmaceutical product manufactured or distributed by answering defendant and nothing was wrongfully taken from such plaintiff or plaintiff's decedent.

- 44. As a forty-third affirmative defense, answering defendant alleges that plaintiff's claims of fraud and concealment are barred by reason of plaintiff's failure to allege the circumstances constituting the alleged fraud and concealment with particularity.
- 45. As a forty-fourth affirmative defense, answering defendant alleges that answering defendant intends to rely upon such other affirmative defenses as may become available or apparent during the course of investigation, discovery, or trial, and answering defendant reserves the right to amend this Answer to assert such other defenses to which it may be entitled

WHEREFORE, answering defendant requests:

- That plaintiff take nothing by the Complaint; 1.
- 2. A dismissal of the Complaint with prejudice and an award of answering defendant's reasonable attorneys' fees to the extent permitted by law;
- Judgment in favor of answering defendant and against plaintiff; 3.
- 4. Costs of suit herein; and
- 5. Such other and further relief that the Court may deem just and proper.

REQUEST FOR JURY TRIAL

Answering defendant respectfully requests a jury trial on those claims to which it is entitled to a jury trial.

Dated: December 5, 2006.

REED SMITH LLP

Kevin M. Hara Attorneys for Defendant Merck & Co., Inc.

A limited liability partnership formed in the State of Delaware

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

PROOF OF SERVICE

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. My business address is REED SMITH LLP, 1999 Harrison Street, Suite 2400, Oakland, CA 94612-3572. On December 5, 2006, I served the following document(s) by the method indicated below:

DEFENDANT MERCK & CO., INC.'S ANSWER TO PLAINTIFF'S UNVERIFIED COMPLAINT AND REQUEST FOR JURY TRIAL

Ш	by transmitting via facsimile on this date from fax number 510.273.8832 the document(s)
	listed above to the fax number(s) set forth below. The transmission was completed before
	5:00 PM and was reported complete and without error.

\square	by placing the document(s) listed above in a sealed envelope with postage thereon fully
	prepaid, in the United States mail at Oakland, California addressed as set forth below. I am
	readily familiar with the firm's practice of collection and processing of correspondence for
	mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same
	day with postage thereon fully prepaid in the ordinary course of business.
	• • • • • • • • • • • • • • • • • • • •

by placing the document(s) listed above in a sealed envelope(s) and by causing personal
 delivery of the envelope(s) to the person(s) at the address(es) set forth below.

by personally delivering the document(s) listed above to the person(s) at the address(es) set
 forth below.

by placing the document(s) listed above in a sealed envelope(s) and consigning it to an express mail service for guaranteed delivery on the next business day following the date of
consignment to the address(es) set forth below.

by transmitting via email to the parties at the email addresses listed below:

ı	Theodore J. Holt, Esq.
ı	David R. Zarka, Esq. Alissa S. Holt, Esq. Hackard & Holt
	Alissa S. Holt, Esq.
I	Hackard & Holt
l	11335 Gold Express Drive, Suite 105
I	Gold River, CA 95670
ı	

Anthony G. Brazil, Esq. Kanika D. Corley, Esq. Morris Polich & Purdy, LLP 1055 West Seventh Street, 24th Floor Los Angeles, CA 90017

Tel:	(916) 853-3000
Fax:	(916) 853-3010

Tel: (213) 891-9100 Fax: (213) 488-1178

Attorneys for Plaintiff

Attorneys for Defendant McKesson Corporation

24 25

26

27

Case 3:07-cv-03493-CRB Document 1-3 File	ed 07/05/2007 Page 15 of 1	5
--	----------------------------	---

1 2 3 4 5 6 7 8	Peter E. Schnaitman, Esq. Tucker, Willis & West 1000 Wilshire Blvd., Suite 1800 Los Angeles, CA 90017-2475 Tel: (213) 430-3400 Fax: (213) 430-3409 Attorneys for Defendants Pfizer, Inc.; Pharmacia Corporation and G. D. Searle LLC I declare under penalty of perjury usabove is true and correct. Executed on December	Anthony G. Brazil, Esq. Kanika D. Corley, Esq. Claudine Horowitz, Esq. Morris Polich & Purdy, LLP 1055 West Seventh Street, 24 th Floor Los Angeles, CA 90017 Tel: (213) 891-9100 Fax: (213) 488-1178 Attorneys for Defendant Amerisourcebergen Drug Corporation ander the laws of the State of California that the 5, 2006, at Oakland, California.
9		
10		Sala a disente
11	_	Sandra A. Lasarte
12		
13		
14		
15		
16		
17		
18		
19		
20		•
21		
22 ·		
23		
24	:	
25		
26		
27		
28		
-	u	